This Page Is Inserted by IFW Operations and is not a part of the Official Record

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

As rescanning documents will not correct images, please do not report the images to the Image Problem Mailbox.



(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization International Bureau



(43) International Publication Date 20 December 2001 (20.12.2001)

PCT

(10) International Publication Number WO 01/95801 A1

(51) International Patent Classification': A61B 5/113, 5/024

(21) International Application Number: PCT/US01/19054

(22) International Filing Date: 14 June 2001 (14.06.2001)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data: 00112681.2

15 June 2000 (15.06.2000) EP

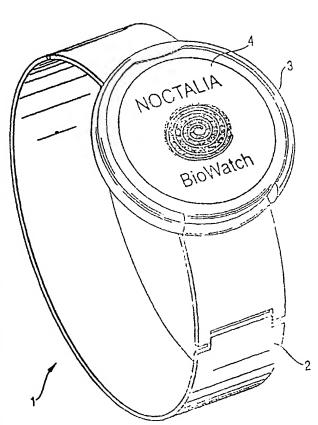
- (71) Applicant (for all designated States except US): THE PROCTER & GAMBLE COMPANY [US/US]; One Procter & Gamble Plaza, Cincinnati, Oll 45202 (US).
- (72) Inventors; and
- (75) Inventors/Applicants (for US only): BARRON, Bradford, S. [US/BE]; Neerhoflaan 35, B-1780 Wemmel

(BE). BOSWELL, Emily, Charlotte [GB/GB]; 45 Harvesters Close, Isleworth, Middlesex TW7 7PP (GB). DAUGER-STRAUSS, Corrine [FR/BE]; Avenue du Commondant Lothaire, B-1040 Brussels (BE). DEFLANDER, Joseph, Fernand [BE/BE]; Elleveldweg 22, B-2990 Wespelaar (BE). MACGILP, Neil, Archibald [GB/GB]; Bankfield, Snowdenham Links Road, Surrey GU5 0BX (GB). VAN DEN WOUWER, Chris [BE/BE]; Bisschoppenhoflaan 400, B-2100 Deurne (BE). EWART, Keith [GB/GB]; 127 Harefield Road, Uxbridge UB8 1PN (GB).

- (74) Common Representative: THE PROCTER & GAM-BLE COMPANY; c/o Mr. T. David Reed, 5299 Spring Grove Avenue, Cincinnati, OH 45217 (US).
- (81) Designated States (national): AE, AG, AL, AM, AT, AT (utility model), AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, CZ (utility model), DE, DE (utility model), DK, DK (utility model), DM, DZ, EE, EE (utility model), ES, FI, FI (utility model), GB, GD, GE, GH,

[Continued on next page]

(54) Title: DEVICE FOR BODY ACTIVITY DETECTION AND PROCESSING



(\$7) Abstract: A device for monitoring body activity and arranged for stand-alone attachment to a body in u.e. The device comprises: an actimetry sensor (11) for measuring body activity, and storage means (12) for receiving data from the actimetry sensor and storing it. Means analyses the stored data to provide advisory information and a display (4) the advisory information to a user.

WO 01/95801 A1



GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SK (utility model), SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.

(84) Designated States (regional): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE,

IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published:

- with international search report

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

DEVICE FOR BODY ACTIVITY DETECTION AND PROCESSING

This invention relates to the detection of body activity, such as sleep patterns, and the analysis of data related to such functions for provision to a user.

In recent years there has been much study of body functions, such as sleep activity, and associated analysis of the relevance of such functions to the general health of the body and the body's need for appropriate body functions (such as sleep patterns) to occur on a regular basis for adequate periods of time. As part of this research numerous devices have been proposed to assist in such measurement and analysis.

For example, WO-A-9714354 discloses a device and corresponding method which collects data for analysing sleep disturbances so that such data can be interpreted by a specialist at a future date.

However, this type of device requires operation by a highly skilled user and provides analysis which is difficult to interpret by anybody other than a specialist, as well as being expensive and sometimes unreliable. Furthermore, it is unable to provide a detailed history over an extended time period for an individual.

Other systems are uncomfortable, cannot be worn for extended periods and/or cannot be worn without restricting body movement.

According to the present invention there is provided a device for monitoring body activity, the device comprising:

an actimetry sensor for measuring body activity; storage means for receiving data to actimetry sensor and storing it; means for analysing the stored data to provide advisory information; and

means for displaying the advisory information to a user.

The actimetry sensor may be an accelerometer such as a piezoelectric accelerometer or a MEMS accelerometer, or may be a simple motion sensor or tilt switch, for example.

The body activity being monitored may be sleep, and/or waking activity.

The storage means may store data from the actimetry sensor together with temporal information. In such a case, the means for analysing the stored data provides processing based upon both body activity information and temporal information to provide advisory information to the user.

The advisory information provided to the user may include an indication of the quality of the activity, such as the quality of the sleep, whether or not the duration of the activity is sufficient, an indication as to whether the total amount of the activity over an extended period is acceptable, as well as other data related to other long term body activity, for example. The device can be configured to detect activity during the day. The body activity that is measured can, as well as being actual time slept, be the number of awakenings, an indication as to how intermittent the sleep was, time taken before sleep, the number of and length of sleep interruptions, sleep proficiency, the number minutes immobile/moving, etc. A selection or all of this information can be provided to identify the least and most active times during the day.

The device may include an input (such as buttons) for receiving input data from a user, such as desired time to go to sleep, the need to awake early for a particular event, as well as possible information relating to the age of the user, their sex, as well as, optionally, additional information such as what they perceive their energy level to be.

The device may have one or more additional sensors to also measure body pulse rate variability, blood pressure variability or other body activities such as eyelid movement or respiration. In this case, sleep phases such as REM, slow light sleep, slow deep sleep, or paradoxical sleep may be monitored.

The device may be configured in the style of a wrist watch, and may be arranged to provide additional information to a user, such as time and date information. The device may have an alarm.

The means for displaying the advisory information may be a liquid crystal display or a plasma display, for example.

An additional sensor may be included for detecting data relating to the environment in which the body is placed.

The quality of the sleep may be defined by a parameter "sleep quality index" (SQI) and may be represented by the equation

$$SQI = C + \sum_{i=1}^{n} C_i P_i$$

In this equation n=12 and the twelve parameters, P_i, may be respectively time in bed, sleep and time, actual sleep, time, actual sleep (%), sleep efficiency, sleep latency, sleep bouts, wake bouts, mean activity score, mean score inactive, mean wake bout time, and wake movement RMS. The constant C may be 52.42 and the constants C_i associated with each of the parameters P_i respectively may be -1.887, 0.572, 2.084, -0.3536, 0.1408, -0.018, 0.183, 0-2469, -1.2126, -0.226, -0.0112 and 0.001238.

Alternatively, the quality of the sleep may be represented by a parameter which may be biased by user supplied estimates. The parameters used in the

biasing process may be time in bed, sleep end time, mean activity score and/or mean score inactive.

The invention is described for use in monitoring sleep patterns, however, it may also be of use in monitoring alternative body activities. For example monitoring daily activity levels to indicate whether the user is achieving sufficient activity in a fitness regime, whilst on a diet, during recuperation or, when bed rest is necessary, the level of activity of a patient determines whether bed sores will be prevented. A further example may be to study the activity of children who suffer attention deficit syndrome. There are many other scenarios where the standard equipment could be used to monitor the activity of people or even pets.

If further sensors were introduced such as a heart rate sensor the device could be used to monitor the heart rate either during sleep, to determine the different phases of sleep or during sports activities to monitor the heart rate without the need for any cumbersome chest band. The device could also be used to determine how stressed somebody was and potentially warn of impending heart problems.

Introduction of a global positioning system in combination with the actimetry sensor would allow the device to be used to track the whereabouts and activity of children, old people (particularly Alzheimer's patients) or perhaps criminals on probation. If the actimetry sensor were used in combination with a clock, the device could be used to help controlling jet lag by recommending the best sleeping habits to cope with a particular difference in the space.

One example of the present invention will now be described with reference to the accompanying drawings, in which:

Figure 1 is a schematic perspective view of a device according to the present invention;

Figure 2 is a schematic diagram showing some of the functionality of the device of Figure 1;

Figure 3 to 6 are diagrams showing two possible displays from the device of Figure 1; and

Figure 7 is a schematic diagram of the internal components of the device of Figure 1.

Referring to Figure 1, a device 1 according to the present invention is, in this example, configured as a wrist watch-style device (although could have a different configuration), with a strap 2 and a component-containing housing 3. On the outer surface of the housing 3 is a display 4, which, in this case, is a liquid crystal display.

Referring to Figure 4, a device 1 of Figure 1 has a number of internal components. The device 1 is powered by a battery 10 (or another form of power supply) which supplies power to the other components of the device 1. An actimetry sensor 11 detects motion in the device 1 and hence motion in the body to which the device 1 is attached in use. The data from the actimetry sensor 11 is passed to a memory 12. A clock 13 also provides temporal data to the memory 12 and to the actimetry sensor 11 if necessary, as well as optionally to a display 4. In addition to the actimetry sensor 11 the device 1 may further comprise additional sensors 15, 16, which may detect blood pressure, pulse rate variability etc. Data from these additional optional sensors 15, 16 may also be forwarded to the memory 12. Data from the memory 12 can be requested from straighting means 17, either on a regulated intermittent, continuous, crocked a regulated basis.

A wide variety of different forms of analysis may be performed by the analysing means 17.

Examples of the types of analysis that may be performed will now be described with reference to Figures 2 to 6.

The actimetry sensor 11 may provide information in relation to sleep duration and the type of sleep to the analysing means 17. By type of sleep this may include the duration of sleep, number of interruptions, motion during sleep, for example. This information can be analysed by the analysing means 17 to provide information to the display form in terms simply of the total number of hours of effective sleep obtained, although it may provide additional information in relation to the quality of the sleep and the expected value of that sleep in terms of an "energy bank". By using data stored in the memory 12 over a number of days, weeks or months, the analysing means 17 may also provide information indicative of accumulated sleep deficit or sleep excess. As mentioned above, the data can be provided to a user as and when requested, and is arranged to be provided in a very simple format so that it does not need complex interpretation.

The analysing means 17 may employ a sleep scale such as the Stanford sleep scale in order to score the monitored sleep and receive relevant information from the user. The scale defines different levels of sleepiness as follows:

- 1 feeling active, vital, alert, wide awake.
- 2 functioning at a high level, not of peak.
- 3 relaxed, not full alertness, remouncive.
- 4 a little soggy, not at peak, let down.
- 5 tired, losing interest, slowed down.
- 6 drowsy, prefer to be lying dinn.
- 7 almost in a reverie, hard to a pawake.

This scale can be shown to a user so that the user can input an indication of how tired they consider themselves to be. For example, the user could be prompted to input an indication as to how they feel when they wake up, with an indication as to the reasons for their feelings being provided by the analysing means 17 from the data collected.

In another example, such an input could be employed during the initial weeks of employing the device to help the device determine whether or not the user is sleeping for the right amount of time to them. For example, on the first day of wearing the device, the device may prompt the user to indicate how much sleep they consider they need. It could then provide information as to the average sleep requirement for someone of their age and sex. However, as the requirements vary from user to user, the device can then monitor sleep over a given period and prompt the user for feedback, not only at that time but also during the day in order to form a sleep diary in the memory of the device. The device may then be configured to adapt the indications that it gives the user based upon the feedback and wake the user at the appropriate time, and then employing a sleep bank once the user's particular requirements have been detailed.

The device 1 may have an alarm 18, which can be used simply to wake the user, in the manner of a normal wrist watch alarm, although it may be activated by the analysing means 17 (in conjunction with a heart rate monitor), when it is detected that an appropriate type of sleep is occurring to ensure gentle waking of the user or waking at a time such that they have less sleep inertia.

If additional sensors 15, 16 are provided then additional analysis can be performed dependent upon the type of sensor. If the sensors detect parameters external to the body, such as light, incation, sound, air temperature, humidity, barometric pressure, then this information may be compared with information relating to body activity in order to adjust their information. If the sensors determine

~

additional body activity, and detect one or more of muscle tonus, skin temperature, galvanic skin response, etc then additional analysis of the quality of the sleep may be provided. As a further example, if a blood pressure sensor is employed then additional indications related to general levels of health and activity not specifically related to sleep alone can be provided by the analysing means. If a pulse rate variability detector is employed then this can assist in determining the type of sleep detected and the quality of that sleep, and can provide further information in relation to whether an acceptable level of aerobic exercise has been performed within the allotted time period, whether it be a day, a week or a month, for example.

If the device 1 provides some form of "sleep bank" indication over a period of time, then the sleep bank may calculate the information to be provided to the user by including a formula such as:

sleep bank (i) = sleep bank (i-1) + (sleep (i) - need) where sleep bank is accumulative of sleep balance on day i, sleep is sleep achieved on the night before day i and need is sleep need (which can change dependent upon other measured parameters, or upon stored data, or can be set manually).

The device 1, being a highly portable unit, may easily be taken periodically, typically fortnightly to an expert sleep analyst for further interrogation and more detailed advice. A download or transmission facility is provided within the device to enable the data to be extracted for this interrogation process.

The sleep expert will provide a more detailed analysis of the user's sleep patterns. For example, in order to provide a measure of sleep quality, as described above, a parameter "sleep our lity ind----" (£.Q.) may be provided. The algorithm for this parameter SQI, is based upon many of the parameters which are easily monitored, or derived by the invention. The algorithm is

S

$$SQI = C + \sum_{i=1}^{n} C_i P_i$$

This algorithm uses twelve parameters and their associated constants (i.e. n=12). The parameters are

Time in bed [*]	Sleep efficiency	Mean wa ke bout time
Sleep end	Sleep latency	Mean activity score
Actual sleep time	Sleep bouts	Mean sco re inactive
Actual sleep (%)	Wake bouts	Wake movement RMS

Corresponding constants may be defined by the values 52.42, -1.887, 0.572, 2.084, -0.3536, 0.1408, -0.018, 0.188, -0.2469, -1.2126, -0.226, -0.0112, 0.001238. Alternatively, this algorithm may be customised to represent an individual user, to achieve results of greater accuracy.

Solution of this algorithm can be intensive in terms of processing requirements. Where the processing capacity is not extensive, as in the analysing means 17 of the device 1, a simpler for hulation may be implemented. In this case, a value for quality of sleep is estimated by the user and this value is modified, based on four of the monitored/derived parameters (those marked) above. This basic interpretation of sleep quality gives a lower predictive accuracy, nevertheless it provides a useful gauge, on a day to day basis, for the user of the device.

CLAIMS

- A device for monitoring body activity, the device comprising:

 an actimetry sensor for measuring body activity;
 storage means for receiving data from the actimetry sensor and storing it;
 means for analysing the stored data to provide advisory information; and
 means for displaying the advisory information to a user.
- 2. A device of claim 1, wherein the actimetry sensor is an accelerometer such as a piezoelectric or MEMS accelerometer.
- 3. A device of claim 1 or 2, wherein the body activity being monitored is sleep.
- 4. A device of any preceding claim, wherein the storage means store data from the actimetry sensor together with temporal information.
- 5. A device of claim 5, wherein the means for analysing the stored data provides processing based upon both body activity information and temporaled information.
- 6. A device of any preceding claim, wherein the advisory information provided to the user includes an indication of the quality of the activity, including at least one of the quality of the sleep, whether or not the durit tion of the activity is sufficient, an indication as to whether the totalled amount of the activity over an extended period is acceptable, or other data related to other long term body activity.
- 7. A device of any preceding claim, further comprising at least one additional sensor measuring at least one or body. Its a rute variability, and/or blood pressure.

8. A device of claim 7, wherein sleep phases of REM, slow light sleep, slow deep sleep, or paradoxical sleep are monitored.

- 9. A device of any preceding claim, wherein the device may be configured in the style of a wrist watch.
- A device of claim 9, wherein the device has an alarm.
- 11. A device of any preceding claim, wherein the means for displaying the advisory information is a liquid crystal display.
- 12. A device of any preceding claim, further comprising a sensor for detecting data relating to the environment in which the body is placed.
- 13. A device according to claim 6, wherein the quality of the sleep is defined by a parameter "sleep quality index" (SQI) represented by the equation

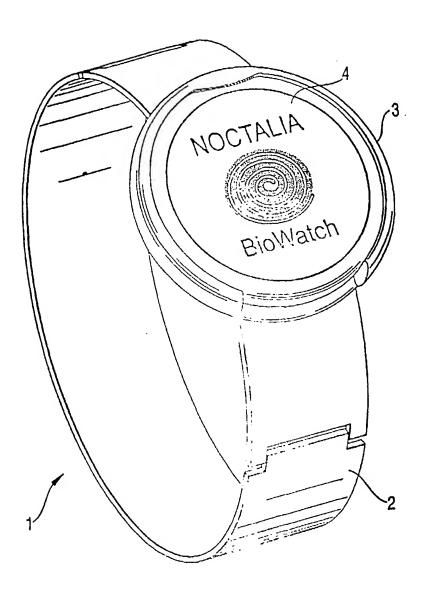
$$SQI = C + \sum_{i=1}^{n} C_i P_i$$

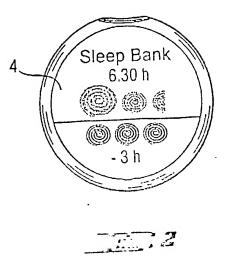
where n=12 and the twelve parameters, P_i , are respectively time in bed, sleep end time, actual sleep time, actual sleep (%), sleep efficiency, sleep latency, sleep bouts, wake bouts, mean activity score, mean score inactive, mean wake bout time, and wake movement RMS.

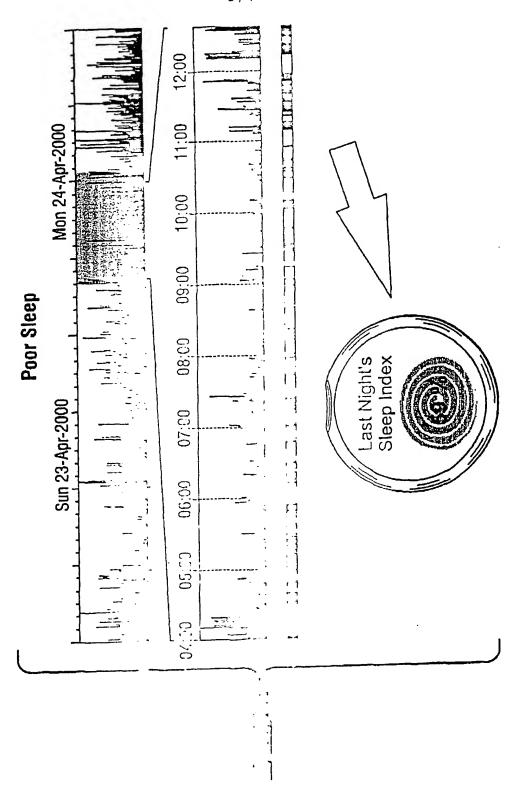
- 14. A device according to claim 13, wherein the constant C is 52.42 and the constants C_i associated with each of the parameters P_i respectively are -1.887, 0.572, 2.084,
- -0.3536, 0.1408, -0.018, 0.188, -0.2469, -1.2126, -0.226, -0.0112 and 0.001238.
- 15. A device according to claim 6, wherein the quality of the sleep is represented by a parameter biased user supplied a timate.

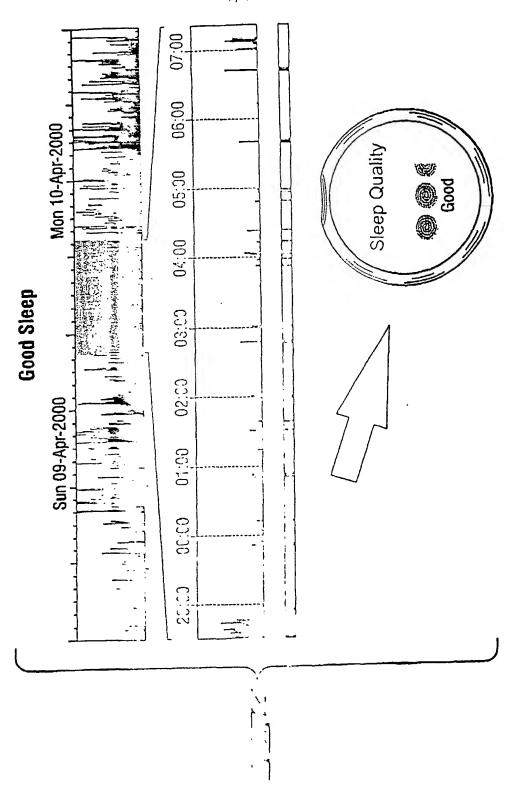
16. A device according to claim 15, wherein the parameters used in the biasing process are time in bed, sleep end time, mean activity score, mean score inactive.

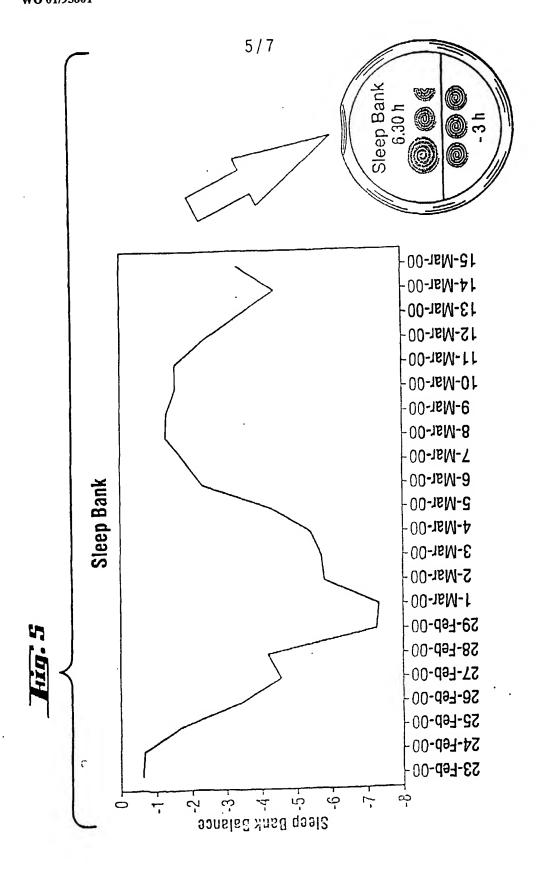
17. A device according to any preceding claim, wherein the device in arranged, in use, for stand-alone attachment to a body.











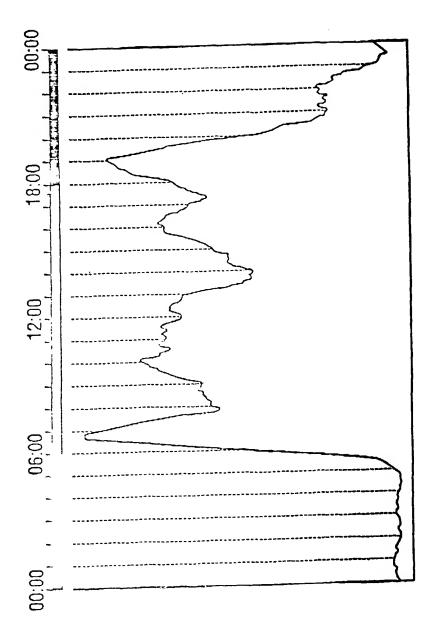
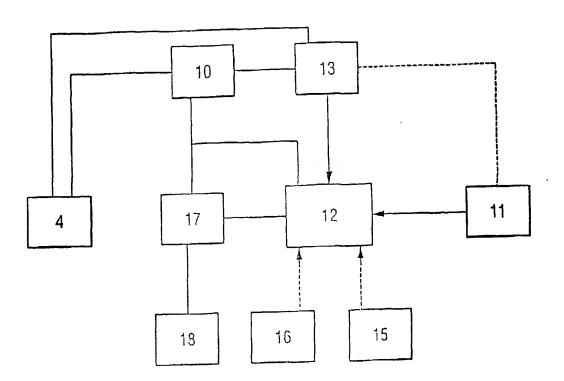




Fig. 7



INTERNATIONAL SEARCH REPORT

ional Application No PCT/US 01/19054

A. CLASSIFICATION OF SUBJECT MATTER IPC 7 A61B5/113 A61B5/024

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

4) 30 - 7

Documentation searched other than minimum documentation to the extent that such documents are included. In the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, BIOSIS, WPI Data, PAJ, INSPEC

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to daim No.
Υ	FR 2 700 683 A (UNIV RETWES)	1-12
	29 July 1994 (1994-07-29)	12 16
Α	page 7, line 6 -page 8, line 14	13,16
	page 10, line 10 -page 13, line 13	
	page 14, line 7 -page 19, line 16; tables	
	1-6	
v	FR 2 679 453 A (UMIV REMMES)	1-12
•	29 Jan uary 1993 (1903-01-29)	1
Α	page 7, line 10 -page 17, line 4; tables	15–17
	1,2	
		1 12
Y	FR 2 727 850 A (ELA MEDICAL SA)	1-12
	14 June 1990 (1990-03-14)	
	page 10, line 3 - line 24	
	<pre>page 8, line 11 - line 13 page 6, line 14 - line 19; table 1</pre>	
	page 0, time 14 - t h- ", table 1	
	-/	[.

Further documents are tisted in the point of American in.	X Patent family members are listed in annex.
Special categories of cited documents: 'A' document defining the general state of the last with the set with the considered to be of particular to the considered to the considere	'T' later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"E" earlier document but published on or a set the interest of all filling date "L" document which may throw doubts on priority claim(s) or which is clied to establish the publication date of another citation or other special reason "as special"; "O" document referring to an oral of the setting us to write the use.	'X' document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to avoive an inventive step when the document is taken alone 'Y' document of particular relevance; the claimed invention 'and be sometimed to involve an inventive step when the country is combined with one or more other such document.
other means 'P' document published prior to the intermediate that the priority date also recommend to the priority date.	the fact, is all combination being obvious to a person skilled of the art. 181 dictional dimember of the same patent family
Date of the actual completion of the hard in the reserve	Direct listing of the international search report
21 August 2001	25/25/2001
Name and mailing address of the ISA European Paters Color, 1911 Facts Pater laan 2 NL ~ 2280 HV Fifter jk Tel. (+31-70) 34 1 - 040 Table 11 - 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1	Puthorized chicer 15 This, J

INTERNATIONAL SEARCH REPORT

Int Honel Application No PCT/US 01/19054

		101/00 02/2001	
C.(Continua Category *	tion) DOCUMENTS CONSIDERED TO BE RELEVANT Citation of document, with indication, where appropriate, of the relevant passages	Relavant to claim No.	
A	US 5 719 825 A (DOTTER JAMES E) 17 February 1998 (1998-02-17) column 1, line 23 - line 51; tables 1,2	1,4,5,7, 9,12,17	
A	DE 196 42 316 A (KRISCHENOWSKI DIRK) 23 April 1903 (1968-19-1) column 3, line 5 - line 54; table 2	1,3,4,8, 10,16	
A	COlumn 3, line 5 - line 50; table 2 BUYSSE D J ET AL: "THE PITTSBURGH SLEEP QUALITY INDEX A WEW INSTRUMENT FOR PSYCHIATRIC TRACTICE ALD RESEARCH" PSYCHIATRY RESEARCH, vol. 28, no. 2, 1999, pages 193-214, XP0010207C0 ISSN: 0165-1721 abstract page 193	6,13	

INTERNATIONAL SEARCH REPORT

information on patent family members

Int. Ional Application No PCT/US 01/19054

Patent document cited in search report	:	Publication date	Patent family member(s)	Publication date
FR 2700683	A	29-07-1994	DE 69419308 D EP 0681447 A WO 9416610 A	05-08-1999 15-11-1995 04-08-1994
FR 2679453	A .	29-01-1993	DE 69223969 D EP 0597032 A WO 9302731 A	12-02-1998 18-05-1994 18-02-1993
FR 2727850	Α	14-06-1996	NONE	
US 5719825	Α	17-02-1998	US 5348027 A	08-12-1998
DE 19642316	Α	23-01-1908	JAC!1	